UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte MICHAEL A. MASINI

Appeal No. 2005-1675
Application No. 09/523,503

ON BRIEF

Before FRANKFORT, NASE, and BAHR, Administrative Patent Judges.
NASE, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection (mailed April 15, 2003) of claims 8 to 16. Claims 1 to 7, the only other claims pending in this application, have been withdrawn from consideration. Subsequent to the final rejection, the examiner withdrew the non-prior art rejections of claims 12 to 16.[1] Consequently, claims 8 to 13, 15 and 16 remain on appeal. Claim 14 would be allowable if rewritten in independent form.

We AFFIRM.

[1] See page 2 of the answer (mailed March 19, 2004).

BACKGROUND

The appellant's invention relates generally to orthopedic surgery and, in particular, to alternative depth referencing in conjunction with knee-replacement surgery (specification, p. 1). A copy of the claims under appeal is set forth in the appendix to the appellant's brief.

The prior art references of record relied upon by the examiner in rejecting the appealed claims are:

Whiteside	4,474,177	Oct. 2, 1984
White	5,662,656	Sept. 2, 1997

Claims 8 to 13, 15 and 16 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Whiteside.

Claims 8 to 13 and 16 stand rejected under 35 U.S.C. § 102(b) as being anticipated by White.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellant regarding the above-noted rejections, we make reference to the final rejection and the answer for the examiner's complete reasoning in support of the

rejections, and to the brief (filed December 22, 2003) for the appellant's arguments thereagainst.

OPINION

In reaching our decision in this appeal, we have given careful consideration to the appellant's specification and claims, to the applied prior art references, and to the respective positions articulated by the appellant and the examiner. As a consequence of our review, we make the determinations which follow.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Verdegaal Bros. Inc. v. Union Oil Co., 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir.), cert. denied, 484 U.S. 827 (1987). The inquiry as to whether a reference anticipates a claim must focus on what subject matter is encompassed by the claim and what subject matter is described by the reference. As set forth by the court in Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 772, 218 USPQ 781, 789 (Fed. Cir. 1983), cert. denied, 465 U.S. 1026 (1984), it is only necessary for the claims to "'read on' something disclosed in the reference, i.e., all limitations of the claim are found in the reference, or 'fully met' by it."

The anticipation rejection based on Whiteside

We sustain the rejection of claims 8 to 13, 15 and 16 under 35 U.S.C. § 102(b) as being anticipated by Whiteside.

Claim 8 on appeal reads as follows:

> A method of resecting a distal femur having prominent and non-prominent condyles separated by a trochlear region, the method comprising the steps of:
> a) installing a fixture onto the distal femur which references the non-prominent condyle or trochlear region; and
> b) resecting the femur in accordance with the reference made in (a).

Whiteside's invention relates to a method of shaping the distal surface of a human femur using certain alignment guides and instruments to prepare that surface to receive a distal femoral prosthesis and also relates to certain apparatus used in that method. Figure 14 is a perspective view of a distal femoral surface showing entry point 148 for a reamer. Figure 14 depicts the distal femoral surface 140 of the right femur showing medial condyle 141, the lateral condyle 142, the intercondylar groove 143, the posterior condylar surface 144, the anterior condylar surface 145 and the patellar surface 146. Circle 148 marks a typical entry point for the intramedullary reamer which is later followed by the femoral alignment guide. Choosing a position lateral to circle 148 will result in slightly more valgus after a femoral prosthesis is implanted while choice of a position medial to circle 148 results in decreased valgus positioning.

Figure 8 of Whiteside is a side view of a femoral surface modifying instrument in the nature of a distal femoral condyle cutting guide 80 having a guideplate 82 having a cutting guide surface 83 held transverse to the central long axis of handle 36 and attached to main body 81 by means of arm 84. Main body 81 contains central passage 85 adapted to cooperatively receive the guide handle 36 (not shown) of intramedullary alignment guide 30 and threaded passage 86 adapted to receive locking bolt 88 to fixedly secure guide handle 36 to the main body 81 in proper alignment with guide 30. Figure 9 of Whiteside shows the cutting guide 80 with guide handle 36 in place and with locking bolt 88 in position to secure main body 81 to guide handle 36. Cutting guide 80 is likewise designed to modify the distal femoral condyles to suit a preselected distal femoral prosthesis.

Whiteside's distal femoral condyle cutting guide 80 is placed on guide handle 36 and moved forward (see Figure 19) until the cutting guide surface 83 (not shown) is positioned to remove the desired amount of bone (approximately the thickness of the distal portion of the femoral prosthesis component). Cutting guide 80 is then secured to handle 36 by means of locking bolt 88. A saw blade 190 having saw teeth 192 is then placed against cutting guide surface 83 (not shown) on the femoral side of guideplate 82 and a rough cut of each of the two distal femoral condyles is made, one cut on each femoral side of guideplate 82. Cutting guide 80 is then removed and the rough cut is

completed if the surgeon was not able to completely cut through the condyles with cutting guide 80 attached.

The appellant's argue (brief, p. 4) that:

> Whiteside is entirely silent with regard to referencing any feature of the distal femur, regardless of whether such features include condyles or trochlear region. In addition, if Whiteside were to reference the non-prominent condyle or trochlear region, more bone would be removed from the most prominent condyle than the thickness of the prosthesis to be inserted, which is contrary to the statements just cited.

The examiner's response to this argument (answer, pp. 3-4) is that:

> Whiteside clearly shows in Figure 19 the fixture, which comprises member 81 and guide 80, referencing, i.e. refers to or indicate, the distal end 140 of the femur and where to cut at the distal end of the femur. Moreover, Whiteside's Figure 19 clearly shows that the fixture references to the trochlear region 143 (see Figures 14 and 19) since it slides along an axis between the condyles 141 and 142 of the femur, thus it indicates that area. Also, the guide 82, which is part of the fixture, indicates or refers to, as shown in Figure 19, the condyle areas, i.e. non-prominent and prominent, where a cut is done (see col. 9 lines 57-61).
>
> In response to applicant's argument (see page 4, lines 23-26 of applicant's Brief) that "if Whiteside were to reference the non-prominent condyle or trochlear region, more bone would be removed from the most prominent condyle than the thickness of the prosthesis to be inserted, which is contrary to the statement" "The cutting guide surface 83 (not shown) is in position to remove the desired amount of bone (approximately the thickness of the distal portion of the femoral prosthesis component).", it is noted that applicant's way of reference to the distal femur is not the only way of "referencing". Moreover, the claims only require "references" to the non-prominent or trochlear region, they do not require "references" in a specific way and the term "references" has not been defined by applicant in any specific way. Moreover, as explained above, Whiteside clearly

> shows referencing to the distal femur, e.g. the non-prominent condyle, the prominent condyle, and the trochlear region, and this is reaffirmed when Whiteside states that "A saw blade 190 having saw teeth 192 is placed against cutting guide surface 83 (not shown) on the femoral side of the guide plate 82 and a rough cut of each of the two distal femoral condyles is made, one cut on each femoral side of guide plate 82." (see col. 9, lines 57-61), thus in order to make the cut the guide 82 must be referencing to the condyles as shown in Figure 19.

In our view, the method steps of claim 8 are readable on Whiteside as follows:

(1) installing a fixture onto the distal femur which references the non-prominent condyle or trochlear region (as shown in Figure 19, the cutting guide 80 (i.e., fixture) is installed onto the distal femur and references the non-prominent condyle or trochlear region by the positioning of the guideplate 82); and

(2) resecting the femur in accordance with the reference made in (1) (as shown in Figure 19, after the cutting guide 80 is positioned onto the distal femur the femur is cut (i.e., resectioned) in accordance with the positioning of the guideplate 82).

For the reasons set forth above by the examiner and this panel, claim 8 is anticipation by Whiteside. Accordingly, the decision of the examiner to reject claim 8 under 35 U.S.C. § 102(b) as being anticipated by Whiteside is affirmed.

In the Grouping of Claims section of the brief (p. 3), the appellant states "that all of the rejected claims stand or fall with claim 8." Accordingly, claims 9 to 13, 15 and 16 fall with claim 8. See In re Young, 927 F.2d 588, 590, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991); In re Wood, 582 F.2d 638, 642, 199 USPQ 137, 140 (CCPA 1978). Thus, it follows that the decision of the examiner to reject claims 9 to 13, 15 and 16 under 35 U.S.C. § 102(b) as being anticipated by Whiteside is also affirmed.

The anticipation rejection based on White

We sustain the rejection of claims 8 to 13 and 16 under 35 U.S.C. § 102(b) as being anticipated by White.

White's invention relates, in general, to instrumentation for and a method of sizing a distal femur and guiding a bone resection tool to make anterior and distal femoral resections. Figure 1 is an exploded perspective view of the instrumentation of the White's invention. Figure 11 is a somewhat diagrammatic lateral view of a distal femur having an intramedullary rod implanted therein, combined with an instrument body, a valgus module and an anterior feeler gauge of the instrumentation of the White's invention. Figure 12 is a somewhat diagrammatic lateral view of a distal femur having an intramedullary rod implanted therein, combined with an instrument body, a valgus module and a resection guide of the instrumentation of the White's invention

with the resection guide positioned for an anterior femoral resection, and showing a bone resection tool for making an anterior femoral resection of the distal femur. Figure 13 is a somewhat diagrammatic transverse sectional view of a Figure 12 with portions thereof omitted for clarity. Figure 14 is a somewhat diagrammatic lateral view of a distal femur having an intramedullary rod implanted therein, showing an anterior femoral resection thereof. Figure 15 is a somewhat diagrammatic lateral view of a distal femur having an intramedullary rod implanted therein, combined with an instrument body, a valgus module and a resection guide of the instrumentation of the White's invention with the resection guide positioned for a distal femoral resection. Figure 16 is a somewhat diagrammatic anterior view of Figure 15. Figure 17 is a somewhat diagrammatic anterior sectional view of Figure 15 with portions thereof omitted for clarity. Figure 18 is a somewhat diagrammatic lateral sectional view of Figure 15 with portions thereof omitted, and showing a bone resection tool for making a distal femoral resection of the distal femur. Figure 19 is a somewhat diagrammatic lateral view of a distal femur after an anterior femoral resection thereof, showing a distal femoral resection thereof.

White's instrumentation 11 is used in conjunction with a distal femur 13 and a bone resection tool 15 such as a typical oscillating saw or the like having a bone resection member 16 such as a saw blade or the like to make a distal femoral cut or

resection 17 by removing a thickness or amount of bone from the distal aspect or surface 19 of the distal femur 13, and to make an anterior femoral cut or resection 21 to remove a thickness or amount of bone from the anterior aspect or surface 23 of the distal femur 13. The instrumentation 11 includes a resection guide 113 for guiding the bone resection tool 15 to perform an anterior femoral resection 21 of the end of the distal femur 13 and a distal femoral resection 19 of the end of the distal femur 13. The instrumentation 11 further includes an anterior feeler gauge 91 for contacting a portion of the anterior aspect 23 of the distal femur 13 to indicate the anterior-to-posterior size of the distal femur.

White teaches (column 8, line 58, to column 10, line 27) the following method

> The preferred method of sizing the end of a distal femur 13, of performing an anterior femoral resection 21 of the distal femur 13, and of performing a distal femoral resection 19 of the distal femur 13 starts with standard preoperative planning to estimate the size of the prosthesis to be implanted by, for example, comparing lateral radiographs of the distal femur 13 with implant templates, etc. The template size that most closely matches the profile of the distal femur 13 on the anterior and posterior aspect is normally chosen. In order to maintain proper quadriceps tension in flexion and extension, the patellar flange should not be radically shifted either anteriorly or posteriorly. The knee joint can then be exposed using a long anterior skin incision and medical parapatellar incision or the like. Any osteophytes should be removed from the intercondylar notch area of the distal aspect 19 of the distal femur 13 with a rongeur or the like to provide a clear view of the wails and roof of the intercondylar notch. An intramedullary cavity 135 can then be prepared in the distal aspect 19 of the distal femur 13, preferably with an entry point in the deepest point of the patellar groove just anterior to the cortical roof of the intercondylar notch. The intramedullary cavity 135 can be started with a pilot point drill and then finished with an intramedullary

reamer or combination intramedullary reamer and intramedullary rod. In any event, the intramedullary rod 37 is then implanted into the intramedullary cavity 135 with the distal end 35 of the intramedullary rod 37 extending outward from the distal aspect 19 of the distal femur 13. The instrument body construct 25 is then assembled using a selected one of the valgus modules 61, 63, 65 based on the desired valgus angle. If full length extremity radiographs or films are available, the appropriate valgus angle may be estimated by the angle formed between the anatomical axis (the longitudinal axis of the femoral shaft) and the mechanical axis (a line extending through the centers of the femoral head, knee joint and angle joint). The valgus angle may also be determined by using an external alignment rod or the like. The desired valgus angle is set by merely mounting the appropriate one of the valgus modules 61, 63, 65 to the instrument body 27 using the lock nut 87, etc. The instrument body construct 25, with the selected valgus module 61, 63, 65, is positioned on the intramedullary rod 37 with the distal end 35 of the intramedullary rod 37 extending through the cavity 67 in the selected valgus module 61, 63, 65, and moved proximately until the planar face portion 30 of the distal aspect abutting surface 29 abuts the distal aspect 19 of the distal femur 13. The assembly is then adjusted until the pointed end 95 of the stylus 93 rests against a portion of the anterior aspect 23 of the distal femur 13 (e.g., preferably against the lateral anterior condyle). The anterior-to-posterior size of the end of the distal femur 13 can then be read from the scale 109. The anterior-to-posterior size thus read corresponds or relates to the proper implant size to be implanted which determines, in part, the thickness of the initial femoral resections. If the reading falls between two sizes, the smaller size is generally indicated.

The anterior feeler gauge 91 is then removed from the instrument body construct 25 and the resection guide 113 is attached to the instrument body construct 25 in the first position by, for example, sliding the T-slot 121 of the resection guide 113 into the T-flange 123 of the second body member 47 of the instrument body 27 and then tightening the lock screw 125 to lock the resection guide 113 to the second body member 47 of the instrument body 27. As indicated hereinabove, the slots 117, 119 may be automatically set at 3.degree. of external rotation. Handles, bone clamps, nails or pins may be used to help hold the assembly firmly in place on the distal femur 13. The second body member 47 may include apertures 137, ears 139, etc., to coact with such Handles, bone clamps, nails or pins, etc. The anterior femoral resection 21 is then cut by passing the bone resection member 16 of the bone resection tool 15

through the appropriate slot 117, 119 of the body member 115 of the resection guide 113.

The resection guide 113 is then removed from the instrument body construct 25, turned up on end and mounted to the instrument body construct 25 in the second position using the pins 129, etc. The resection guide 113 may then adjusted for more or less resection if so desired. Bone clamps, nails or pins may be used to hold the resection guide 113 firmly in place on the distal femur 13. Thus, for example, the resection guide 113 can be securely pinned to the distal femur 13 by inserting one or more headless bone pins 141 or the like through apertures 143 in the body member 115 and into the distal femur 13 as shown in FIG. 18. The instrument body construct 25 and intramedullary rod 135 may then be removed from the distal femur 13. The thickness of the distal femoral resection 17 should be equal to the thickness replaced by the distal condyle of the implant unless special ligament problems dictate otherwise. For example, a significant flexion contracture may require one to three millimeters of additional distal femoral resection. Recurvatum may require one to three millimeters less distal femoral resection. The distal femoral resection 17 is then cut by passing the bone resection member 16 of the bone resection tool 15 through the appropriate slot 117, 119 of the body member 115 of the resection guide 113. Once the distal femoral resection 17 has been completed, the resection guide 113 can be removed from the distal femur 13 and various additional resections or cuts can be made including, for example, an anterior flange or condylar cut, an anterior bevel cut or cuts, a posterior cut or cuts, a posterior bevel cut or cuts, a patellar track groove cut, a posterior stabilized cut, etc., to prepare the distal femur 13 to receive a trial prosthesis, etc.

The appellant's argue (brief, p. 5) that:

Although the White patent does disclose a reference guide 91, this is used to measure the anterior-posterior thickness of the distal femur to determine the cuts for a particular size implant, and has nothing to do with measuring the distal extent of either condyle or the trochlear region. Reference is made to Figure 11 of White, for example, which clearly shows the way in which the reference guide 91 is used on the anterior side of the bone. In addition, reference is made to column 9, lines 34-39, where it is explained that:

> ".. . valgus module 61, 63, 65 [is] moved proximately until the planar face portion 30 of the distal aspect of butting surface 29 abuts the distal aspect 19 the distal femur 13."
>
> Accordingly, such a structure cannot possibly contact either the non-prominent condyle or trochlear region.

The examiner's response to this argument (answer, pp. 4-5) is as follows:

> In response to applicant's argument that White' s guide 91 "has nothing to do with measuring the distal extent of either condyle or the trochlear region." (see page 5, lines 14-16 of applicant's Brief), the limitations on which the Applicant relies are not stated in the claims. Therefore, it is irrelevant whether the reference includes those features or not.
>
> In response to applicant's argument that White discloses a guide 91 which cannot possibly contact the non-prominent condyle or trochlear region, it is noted that White disclose a fixture (see Figure 1), i.e. 11, which includes a movable member and cutting guide 113. The fixture clearly is mount[ed] or installed onto a distal femur (see Figures 11-18) and the fixture refers to or indicate the condyles at the end of the femur. Moreover, Figure 17 shows the fixture touching the non-prominent condyle region 29.

In our view, the method steps of claim 8 are readable on White as follows: (1) installing a fixture onto the distal femur which references the non-prominent condyle or trochlear region (as shown in Figure 11, the anterior feeler gauge 91 (i.e., fixture) is installed onto the distal femur and references the anterior aspect or surface 23 of the distal femur 13 which inherently also references the non-prominent condyle or trochlear region); and

(2) resecting the femur in accordance with the reference made in (1) (as shown in Figures 11-19, the distal femur is cut (i.e., resectioned) in accordance with the positioning of the anterior feeler gauge 91).

For the reasons set forth above by the examiner and this panel, claim 8 is anticipation by White. Accordingly, the decision of the examiner to reject claim 8 under 35 U.S.C. § 102(b) as being anticipated by White is affirmed.

In the Grouping of Claims section of the brief (p. 3), the appellant states "that all of the rejected claims stand or fall with claim 8." Accordingly, claims 9 to 13 and 16 fall with claim 8. Thus, it follows that the decision of the examiner to reject claims 9 to 13 and 16 under 35 U.S.C. § 102(b) as being anticipated by White is also affirmed.

CONCLUSION

To summarize, the decision of the examiner to reject claims 8 to 13, 15 and 16 under 35 U.S.C. § 102(b) as being anticipated by Whiteside is affirmed; and the decision of the examiner to reject claims 8 to 13 and 16 under 35 U.S.C. § 102(b) as being anticipated by White is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

Charles E. Frankfort

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